UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

BENJAMIN DRESNER, individually and on behalf of all others similarly situated, Plaintiff, v. SILVERBACK THERAPEUTICS, INC., LAURA K. SHAWVER, JONATHAN PIAZZA, RUSS HAWKINSON, PETER THOMPSON, VICKIE L. CAPPS, ROBERT HERSHBERG, SAQIB ISLAM, ANDREW POWELL, JONATHAN ROOT, THILO SCHROEDER, and SCOTT PLATSHON, Defendants.	CASE NO. C21-1499 MJP ORDER ON DEFENDANTS' MOTION TO DISMISS SECOND AMENDED CLASS ACTION COMPLAINT

This matter comes before the Court on Defendants' Motion to Dismiss the Second Amended Class Action Complaint. ("Motion" (Dkt. No. 47).) Having reviewed the Motion, Plaintiffs' Response ("Response" (Dkt. No. 51)), the Reply ("Reply" (Dkt. No. 54)), and all

other supporting materials and documents, the Court GRANTS Defendants' Motion and DISMISSES the Second Amended Class Action Complaint with prejudice.

BACKGROUND

Defendant, Silverback Therapeutics ("Silverback"), is a biopharmaceutical company that developed SBT6050, an Antibody-Drug Conjugate. (Second Am. Compl. ("SAC") ¶ 47 (Dkt. No. 45).) Antibody-drug conjugates consist of a payload (a small molecule drug), and an antibody that is engineered against a specific antigen. (Id.) The payload and the antibody are joined by a chemical linker. (Id.) When an antibody-drug conjugate binds to the target antigen, the payload is released and affects the targeted cell, ideally minimizing the effect on non-targeted cells. (Id.) SBT6050 is a TLR8 agonist linker-payload conjugated to a HER2-directed monoclonal antibody that targets tumors, such as breast, gastric, and non-small cell lung cancers. (Id.)

Before drugs candidates like SBT6050 can be sold commercially, it must first undergo three phases of clinical trials. (Motion at 2.) Phase 1 trials test the drug's safety, dose tolerance, and other properties. (Id.) Silverback's "Phase 1/1b Trial" was designed to evaluate SBT6050's safety, tolerability, pharmacokinetics ("PK"), pharmacodynamics ("PD"), and anti-tumor activity for the treatment of advanced or metastatic HER2-expressing solid tumors in patients for whom all available therapies associated with clinical benefit had failed. (Id.) And because Silverback designed SBT6050 to induce the immune system to kill cancer cells without harming healthy cells, identifying the optimal dosages was critical. (Id. at 3.) Accordingly, the Phase 1/1b Trial was designed to evaluate the safety and tolerability of SBT6050 through a series of dose-escalation studies in monotherapy (utilizing the drug by itself) and combination therapy (using

the drug in combination with other drugs), that Silverback anticipated to continue for more than two years. (Id.)

Silverback designed the trial to proceed through four parts with data from each cohort informing the dose escalation for the proceeding cohorts. (Id.) Part 1 began with monotherapy doses escalating from 0.3 mg/kg, 0.6 mg/kg, 0.9 mg/kg, to 1.2 mg/kg. (Id.) Part 2 was supposed to provide monotherapy in tumor-specific cohorts, using the optimal dose identified in Part 1. (Id.) Part 3 provided combination therapy with pembrolizumab ("pembro") doses escalating from 0.15 mg/kg, 0.3 mg/kg, to 0.6 mg/kg. (Id.) Finally, Part 4 intended to provide combination therapy with pembro in tumor-specific cohorts, using the optimal dose identified in Part 3. (Id.) The clinical sites administering these tests were located in the U.S., Australia, and South Korea, and patients received CT scans every eight weeks until week twenty-four and then every sixteen weeks thereafter. (Id.) Silverback began its Phase 1/1b Trial in July 2020. (SAC ¶ 3.)

A. Silverback's Initial Public Offering

Silverback's Initial Public Offering ("IPO") took place on December 3, 2020, five months after it commenced the Phase 1/1b Trial. (Motion at 3.) Silverback filed a registration statement and a prospectus (collectively "Offering Documents") with the Securities and Exchange Commission ("SEC") in connection with its IPO. (SAC ¶ 4.) Pursuant to the Offering Documents, Silverback conducted the IPO, issuing 11.5 million shares of common stock priced at $21.00 per share. (Id.) Through the Offering Documents, Silverback disclosed that six patients were enrolled in the first, lowest-dose cohort of Part 1 – monotherapy at 0.3 mg/kg every two weeks. (Motion at 3-4.) At the time of the IPO, one of the six patients had stable disease at scans at eight weeks and sixteen weeks, another patient had a reduction in the diameter of her target lesions at eight weeks, and two patients had withdrawn from the trial. (Id. at 4.) Silverback

further disclosed that "changes in the PD markers consistent with the potential mechanism of action have been observed in the first dose cohort, including increases in plasma levels of CRP (C-reactive protein), MCP-1, IP-10 and IL-6, which are indicative of myeloid cell activation and IFNγ, a marker for T and NK cell activation." (Id.) Silverback also discussed its second drug candidate, SBT6290, which expands on the potential of a TLR8 agonist as a payload and utilizes the same mechanism as SBT6050 to activate immune cells for localized tumor treatment. (Motion at 4; SAC ¶ 6.)

Plaintiffs allege the Offering Documents were negligently prepared and misled investors in violation of Section 11 of the Securities Act of 1933 ("Securities Act"). (SAC ¶ 7.) Specifically, Plaintiffs allege that though the Offering Documents discuss changes in the PD markers and SBT6290, Silverback and the individual Securities Act Defendants failed to disclose that patients treated thus far in the Phase 1/1B Trial only exhibited limited anti-tumor activity despite the observed changes and that if SBT6050 failed then Silverback would have to discontinue clinical programs for both SBT6050 and SBT6290. (Id.)

B. Silverback's Statements from March 2021 – August 2021

On March 29, 2021, Silverback filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the 2020 year. (SAC ¶ 66.) The 10-K filing reiterated the observed changes in PD markers from the first monotherapy dose cohort, and that these changes were associated with tumor regression in preclinical studies. (Motion at 5.) It also discussed the safety data emerging from the trial, detailing the most common adverse events (side effects) included flu-like symptoms (fever, chills, nausea, vomiting, fatigue), and redness and swelling at the injection site. (SAC ¶ 68.) The 10-K filing stated that Silverback anticipated providing an update on interim data in the second half of 2021. (Motion at 5.)

In conjunction with the 10-K filing, Silverback issued a press release announcing the Company's fourth quarter and full 2020 financial results and recent corporate updates. (SAC ¶ 70.) The press release stated that "pharmacological activity was observed in the first dose cohort" and "[c]hanges in the pharmacodynamic markers consistent with potential mechanism of action have been observed in patients treated in the first monotherapy dose cohort." (Id.)

Plaintiffs allege the 2020 10-K and corresponding press release statements that disclosed the changes in the PD markers and potential mechanism of action misled Silverback's investors by failing to disclose that, though these same changes in PD markers had been associated with tumor regression in preclinical studies and non-human primate studies, patients treated with SBT6050 as a monotherapy in the first dose cohort only exhibited limited anti-tumor activity. (SAC ¶ 71.) Plaintiffs also allege that Silverback's statement regarding safety data misled investors because patients treated in Part 3 of the trial with SBT6050 in combination with prembro suffered cytokine related adverse events, which meant that SBT6050 used in conjunction with pembro did not have a manageable safety profile. (Id. at ¶ 72.) Lastly, Plaintiffs allege the documents failed to reveal that is SBT6050 trial failed, Silverback would have to discontinue the clinical programs for both SBT6050 and SBT6290. (Id. at ¶ 73.)

Silverback later filed 10-Qs in May and August 2021. (Motion at 5.) Silverback announced in May that SBT6050 continued to advance through monotherapy and pembro combination dose escalation arms, and that changes in the PD markers in the first dose cohort had been observed. (Id.; SAC ¶ 74.) In August, Silverback reiterated it had "observed changes in the PD markers in the first monotherapy dose cohort." (Id.; SAC ¶ 78.) Plaintiffs allege these statements misled investors because patients only exhibited limited anti-tumor activity. (SAC ¶¶ 75, 79.)

C. Silverback's Statements from September to November 2021

On September 13, 2021, Silverback disclosed the interim results of the Phase 1/1b Trial via a press release and an abstract for an upcoming European Society for Medical Oncology ("ESMO") presentation. (SAC ¶ 81.) The Abstract indicated the data reported therein had a cutoff date of April 4, 2021, and explained "that 18 patients across 10 tumor types were treated at 4 dose levels in monotherapy and combination therapy and that dose levels ranging from 0.15 mg/kg to 1.2 mg/kg were pharmacologically active as demonstrated by the induction of blood-based biomarkers associated with myeloid cell and NK or T cell activation." (Id. at ¶ 82; Motion at 5.) Of the 18 patients, 14 were evaluable, of which one demonstrated a partial response and three demonstrated stable disease. (Id.; Motion at 5.) The Abstract also reported on safety data and reported that the most common adverse events were flu-like symptoms consistent with immune activation. (Id. at ¶ 83; Motion at 5-6.) Dose limiting toxicities were observed, but resolved with supportive care, and based on this preliminary safety data, Silverback believed SBT6050 had a manageable safety profile. (Id.) On this news Silverback's stock price dropped from $19.44 to $14.90 per share. (Motion at 6.)

Three days later, Silverback presented the interim results at ESMO based on clinical data as of August 1, 2021. (Motion at 6.) Silverback disclosed "the doses, treatment duration, and tumor-response rates for six specific patients, concluding that SBT6050 conferred clinical benefit to patients with heavily pre-treated, advanced, solid tumors." (Id.) With this information, Silverback also disclosed that forty patients enrolled across five dose levels had been evaluated, "allowing for robust safety, pharmacokinetic, and PD evaluation." (SAC ¶ 87.) Of the forty patients, only thirteen remained on treatment as of August 1, 2021. (Id.) The presentation further revealed that seventeen patients discontinued the treatment due to disease progression, seven

discontinued treatment because they withdrew consent for unidentified reasons, and five patients died due to disease progression. (Id.) Of the evaluable patients, only one patient showed a partial response, and seven had stable disease. (Id.) Silverback also reiterated that SBT6050 had a manageable safety profile. (Id. at ¶ 89.) Following the presentation, Silverback's stock once again fell, this time by 23% to close at $12.50 a share. (Id. at ¶ 90.)

On November 10, 2021, Silverback filed its 10-Q for the third quarter 2021 and informed investors that three patients treated with higher doses of SBT6050 in combination therapy experienced serious dose-limiting toxicities, including one patient death. (Motion at 6.) Silverback reported that it would continue combination therapy at a lower dose for which no dose-limiting toxicities were observed, and which interim data had shown activated myeloid cells and had early signals of anti-tumor activity. (Id.)

Plaintiffs allege these statements misled investors because trial data demonstrated limited tumor activity, that SBT6050 used in conjunction with prembro did not have a manageable safety profile, and finally, that Silverback failed to reveal that if SBT6050 were to be discontinued then so would SBT6290. (SAC ¶¶ 93, 95, 97.)

D. March 2022: Silverback Ceases Development of SBT6050 and SBT6290

On March 31, 2022, Silverback filed its 10-K for fiscal year 2021. (Motion at 6.) It announced it had discontinued the SBT6050 trial after a review of the entire of body of data revealed limited monotherapy anti-tumor activity and cytokine-related adverse events that limited the dose in combination with pembro. (SAC ¶ 98.) Based on this data, Silverback also decided to discontinue SBT6290 due to the likelihood of failure because it had a similar clinical profile to SBT6050. (Id.) On this news, Silverback's stock dropped 8.55% to close at $3.20. (Id. at ¶ 99.)

Plaintiffs bring this class action alleging negligence and securities fraud based on the premise that Silverback and the individually named Defendants knew or should have known SBT6050 was not safe or effective as an anti-tumor drug and failed to disclose SBT6290's success was tied to SBT6050's success. Plaintiffs formulated their claims as actions under sections 11 and 15 of the Securities Act of 1933 ("Securities Act"); sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"); and SEC Rule 10b-5. Plaintiffs' Securities Act claims pertain only to the Offering Documents, which Plaintiffs allege were prepared negligently. Plaintiffs' Exchange Act claims encompasses all filings, press releases, and statements made during the entire class period from March 29, 2021, to March 31, 2022.

ANALYSIS

A. Incorporation by Reference and Judicial Notice

Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6). Lee v. City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001).

The parties previously requested the Court incorporate by reference and take judicial notice of several documents, which the Court granted with the exception of one document. Defendants once again ask the Court to incorporate and take judicial notice of several documents. (Dkt. No. 49.) Plaintiffs do not oppose the request.

A court may take judicial notice of facts that are "not subject to reasonable dispute," Fed. R. Evid. 201(b), as well as documents that are referred to in the complaint, that are central to the plaintiff's claims, and whose authenticity is not disputed. See, e.g., Branch v. Tunnell, 14 F.3d 449, 454 (9th Cir. 1994) overruled on other grounds by Galbraith v. Cty of Santa Clara, 307 F.3d 1119, 1127 (9th Cir. 2002). A court may also take judicial notice of public documents filed with

the SEC, Metzler Inv. GMBH v. Corinthian Colleges, Inc., 540 F.3d 1049, 1065 n. 7 (9th Cir. 2008), undisputed matters of public records, Lee, 250 F.3d at 689, records and reports of administrative bodies, Mack v. South Bay Beer Distributors, 798 F.2d 1279, 1282 (9th Cir. 1986), overruled on other grounds by Astoria Fed. Sav. And Loan Ass'n v. Solimino, 501 U.S. 104, 110-11 (1991), and accounting standards, In re Asyst Tech, Inc. Derivative Litig., No. C-06-04669 EDL, 2008 WL 2169021, at *1 n. 1 (N.D. Cal. May 23, 2008).

Defendants ask the Court to incorporate by reference Exhibits A-S attached to the Declaration of Koji Fukumura. (Dkt. No. 48.) Exhibits A-S are all Silverback's SEC filings and statements, on which Plaintiffs' allegations are based. The Court previously incorporated these by reference and will do so again as these are referred to extensively in the SAC. The Court GRANTS Defendants request as to Exhibits A-S.

Defendants then ask the Court to take judicial notice of Exhibits T-Y. Exhibits T-V are analyst reports published during the Class Period. Courts have regularly taken judicial notice of analyst reports, not for the truth of the matter asserted, but "for the purpose of showing that particular information was available to the stock market." Helitrope Gen., Inc. v. Ford Motor Co., 189 F.3d 971, 981 n.18 (9th Cir. 1999); see also, In re Apple Inc. Sec. Litig., No. 19-cv-02033-YGR, 2020 WL 2857397, at *6 (N.D. Cal. June 2, 2020) (noting that courts routinely take judicial notice of analyst reports and providing list of cases). The Court GRANTS Defendants' request as to these Exhibits.

Exhibits W and X are government resources. Exhibit W is a guidance document detailing good clinical practices for trials such as Silverbacks and Exhibit X is the National Cancer Institute's definition of an "open-label study." Exhibit Y is a publication by PharmaSUG, entitled Implementation of Data Cut off in Analysis of Clinical Trials. While the parties'

understanding of what an open-label study is in dispute, the Court will take judicial notice of these documents for the purpose of understanding what is generally understood by "open-label" and best clinical practices. The Court GRANTS Defendants' request as to these Exhibits.

B. Motion to Dismiss

1. Legal Standard

Under Fed. R. Civ. P. 12(b)(6), the Court may dismiss a complaint for "failure to state a claim upon which relief can be granted." In ruling on a motion to dismiss, the Court must construe the complaint in the light most favorable to the non-moving party and accept all well pleaded allegations of material fact as true. Livid Holdings Ltd. v. Salomon Smith Barney, Inc., 416 F.3d 940, 946 (9th Cir. 2005); Wyler Summit P'ship v. Turner Broad. Sys., 135 F.3d 658, 661 (9th Cir. 1998). Dismissal is appropriate only where a complaint fails to allege "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim is plausible on its face "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

2. Section 11 Claim

a. Elements of Claim

Section 11 of the Securities Act creates a private remedy for any purchaser of a security if the registration statement published in connection with the offering "contain[s] an untrue statement of a material fact or omit[s] to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). To prevail on a section 11 claim, a plaintiff must prove "(1) that the registration statement contained an omission or misrepresentation, and (2) that the omission or misrepresentation was material, that is, it would have misled a reasonable investor about the nature of his or her investment." In re Daou

Sys., Inc., 411 F.3d 1006, 1027 (9th Cir. 2005) (internal quotation and citation omitted). Under section 11, "[l]iability against the issuer of a security is virtually absolute, even for innocent misstatements," if the plaintiff can show a material misstatement or omission. Herman & MacLean v. Huddleston, 459 U.S. 375, 382 (1983).

b. Applicable Pleading Standards

Defendants move to dismiss Plaintiffs' section 11 claim arguing that it is subject to Federal Rule of Civil Procedure 9(b)'s heightened pleading standard and that Plaintiffs have failed to meet that standard. The Court agrees.

Federal Rule of Civil Procedure 8(a) typically applies to a section 11 claim because they do not require an allegation of scienter. Daou, 411 F.3d at 1027. But if the section 11 claim sounds in fraud, the complaint must satisfy the particularity requirements of Federal Rule of Civil Procedure Rule 9(b). Rubke v. Capital Bankcorp LTD, 551 F.3d 1156, 1161 (9th Cir. 2009). "To ascertain whether a complaint sounds in fraud, we must normally determine, after a close examination of the language and structure of the complaint, whether the complaint alleges a unified course of fraudulent conduct and relies entirely on that course of conduct as the basis of a claim." In re Rigel Pharms, Inc. Sec. Litig., 697 F.3d 869, 885 (2012) (internal quotation and citation omitted). When a complaint employs the exact same factual allegations to allege violations of section 11 as it uses to allege fraudulent conduct under section 10(b) of the Exchange Act, we can assume that it sounds in fraud. See Daou, 411 F.3d at 1028. A plaintiff cannot escape the requirements of Fed. R. Civ. P. 9(b) with a general disclaimer that a claim is based on negligence rather than fraud. Wagner v. First Horizon Pharm. Corp., 464 F.3d 1273, 1278 (11th Cir. 2006); In re Stratosphere Sec. Litig., 1 F.Supp.2d 1096, 1104 (D. Nev. 1998).

In the Court's previous order dismissing Plaintiffs' first amended complaint, the Court found that Rule 9 applied to Plaintiffs' section 11 claim because the class period for Plaintiffs'

section 10(b) fraud claim began with the IPO and because Plaintiffs relied on the same factual allegations for their section 11 claim as they did their section 10(b) claim. In the SAC, Plaintiffs changed the class period to begin with Silverback's March 10-K filing, but they continue to rely on the same factual allegations for their fraud claim as they do their section 11 claim.

Plaintiffs allege the Offering Documents were negligently prepared because Silverback failed to disclose that patients treated with SBT6050 as a monotherapy in the first dose cohort only exhibited limited anti-tumor activity despite the observed changes in the PD markers. (SAC ¶ 64.) Plaintiffs also claim the Offering Documents failed to inform investors that "if SBT6050 did not demonstrate more than limited anti-tumor activity as a monotherapy in Phase 1/1b testing, the Company would have to discontinue the clinical programs for both SBT6050 and SBT6290." (Id.) With regard to the first allegation, Plaintiffs claim that because the trial was open label, Silverback knew patient scans showed limited tumor activity but failed to disclose it. (Id. at ¶ 62.)

These same omissions and Plaintiffs' reliance on the trial's open label as evidence are repeated in Plaintiffs 10(b) claim. For example, Plaintiffs highlight the following excerpt regarding changes in PD markers from the Offering Documents:

> "This includes increases in plasma levels of CRP (C-reactive protein), a marker of inflammation, increases in MCP-1, IP-10 and IL-6, which are indicative of myeloid cell activation, increases in IFNg which is a marker for T and NK cell activation, and decreases in hemoglobin which we believe to be due to macrophage phagocytosis."

(SAC ¶ 61.)

This same paragraph is contained in Silverback's March 2021 10-K filing, which Plaintiffs extracted to argue that though Silverback reported changes in the PD markers, it failed to disclose that "patients treated with SBT6050 as a monotherapy in the first dose cohort of the

Phase 1/1b trial only exhibited limited anti-tumor activity despite observed changes in the [PD] markers." (SAC ¶ 71.) Silverback continued to repeat that it had "observed changes in [PD] markers in the first dose cohort" in its other filings. (See id. at ¶¶ 74, 78, 92.) Plaintiffs allege each of these statements are misleading for the same reason they were misleading in the Offering Documents. (See id. at ¶¶ 75, 79, 93.) And Plaintiffs purported evidence for demonstrating the falsity of these statements is the trial's open label status.

The same pattern applies to Silverback's statements on SBT6290. Plaintiffs allege that all of Silverback's statements as to SBT6290 omitted the same thing: "if SBT6050 did not demonstrate more than limited anti-tumor activity as a monotherapy in Phase 1/1b testing, the Company would have to discontinue the clinical programs for both SBT6050 and SBT6290 given that they both utilize the TLR8 agonist as a payload (i.e., function using the same mechanism to activate immune cells for targeted tumor treatment)." (SAC ¶ 64.) Plaintiffs claim Silverback omitted this information in both the Offering Documents and during the class period. (See id. ¶¶ 64, 73, 77, 97.) Despite making the same omissions, Plaintiffs fail to explain how the omission made in the Offering Document was negligent, but fraudulently made during the class period.

Plaintiffs' SAC alleges the same misleading statements and omissions for both the section 11 claim and the section 10(b) claim. And Plaintiffs suggest the same evidence would be used as well for both claims. Because Plaintiffs' claims allege the same factual allegations and evidence for both claims, the Court finds Plaintiffs' section 11 claim is grounded in fraud and must meet the heightened pleading requirements of Rule 9(b).

c. Plaintiffs' Section 11 Claim Fails to Satisfy Rule 9(b)

In order to satisfy Rule 9(b)'s pleading requirements, Plaintiffs must "state with particularity the circumstances constituting fraud. . ." Fed. R. Civ. P. 9(b). In other words, the

complaint must "set forth what is false or misleading about a statement, and why it is false." Yourish v. Cal. Amplifier, 191 F.3d 983, 993 (9th Cir. 1999).

Plaintiffs identify two statements that were omitted from the Offering Documents that make them materially false and misleading. The first statement deals with the efficacy of SBT6050. As discussed above, Plaintiffs allege that even though Silverback discusses observed changes in the PD markers in the first dose cohort and that such changes are consistent with potential mechanism of action, Silverback failed to disclose that patients in the first dose cohort only exhibited limited anti-tumor activity. (SAC ¶¶ 61, 64.) In support of this claim, Plaintiffs point to statements in the Offering Documents that claim one of the six patients from the first dose cohort had stable disease and another had "target lesion reduction," which gave investors the false impression that SBT6050 showed early signs of efficacy. (Id. at ¶ 62.) Plaintiffs claim that Silverback knew the other four patients demonstrated disease progression but did not disclose this information. (Id.) Plaintiffs base this belief on Silverback's access to the open label data and allege that by April 4, 2021, all six of the patients from the first done cohort withdrew due to disease progression. (Id.)

Defendants argue Plaintiffs are attempting to plead fraud by hindsight. The Court agrees. "A claim under section 11 based on the omission of information must demonstrate that the omitted information existed at the time the registration statement became effective." Rubke, 551 F.3d at 1164 (internal citation omitted). Plaintiffs argue that by April 4, ten out of fourteen trial participants in the two dose cohorts had experienced disease progression, and the most logical inference of this is that Silverback knew at the time of the IPO that the data not only demonstrated limited anti-tumor activity, but also disease progression. (Response at 12.) But

Plaintiffs pointing to patient withdrawals by April 4, 2021, fails to demonstrate falsity because it uses data that had a cutoff date that occured four months after the IPO.

Plaintiffs then argue the inference is supported by the trial data. Though the Offering Documents reported the tumor status of only two patients, neither of whom experienced disease progression, Plaintiffs argue that the ESMO presentation revealed that at least two other first dose cohort patients had been evaluated prior to the IPO. (Response at 12.) But a review of the data does not support this. Plaintiffs point to Silverback's ESMO presentation, which reported on the first dose cohorts' results. (See Declaration of Tamar Weinrib, Exhibit A at 20 (Dkt. No. 52-1).) The data from this presentation had a cutoff date of August 1, 2021. (Id.) And while the study reports on five patients from the first dose cohort it does not say when the patients began receiving doses. Though the first dose cohort treatment began in July 2020, that too does not mean that all patients from the first dose cohort began at that time. Rather, the Registration Statement disclosed that as of November 25, 2020, six patients had been enrolled at 0.3 mg/kg and had received between one and nine doses. (Declaration of Koji Fukumura, Exhibit C at 129 (Dkt. No. 48-8).) Two of the first four patients had to be replaced after the trial began. (Id.) The most logical inference of this is that not all patients had been on SBT6050 long enough to receive scans and be evaluated. And while all first dose cohort patients ultimately were evaluated, Plaintiffs fail to put forth anything to suggest that Silverback evaluated more than two of them by the time of the IPO.

Finally, even assuming more than two patients had been evaluated, disease progression does not necessarily make Silverback's statements false or misleading. In order to prevail on their claim, Plaintiffs must prove that the omission "would have misled a reasonable investor about the nature of his or her investment." Daou, 411 F.3d at 1027. Silverback argues that even if

Silverback had data showing disease progression, a reasonable investor would not be surprised by such a report given that the first dose cohort were on the lowest dose and all the patients had advanced metastatic tumors and failed all prior therapies. (Reply at 4.) The Court agrees. Plaintiffs appear to mistake correlation for causation. Silverback's statements repeatedly make clear that the changes in PD markers are "consistent with the potential mechanism of action" and the changes "had been associated with tumor regression." (SAC ¶¶ 61, 64.) These statements are a far cry from an absolute statement declaring the drug efficacious. A reasonable investor able to follow and understand the technicalities of a cancer drug's development would not construe statements that discuss the "potential mechanism of action" and "associations with tumor regression" as claims of efficacy. And it is likely a reasonable investor would even expect to see limited anti-tumor activity in patients with advanced diseases on the lowest dose of a trial drug. For all these reasons, Plaintiffs fail to demonstrate falsity with regard to these statements.

Plaintiffs' second omission deals with Silverback's failure to disclose that SBT6290's future success depended on SBT6050's success. (SAC ¶ 64.) Plaintiffs argue that once Silverback opted to speak about SBT6290, it incurred an obligation to disclose the company could not develop SBT6290 if SBT6050's trial data reflected a lack of efficacy and/or unmanageable safety problems, given that both the drugs used the same TLR8 agonist as a payload. (Response at 13.) But a wholistic view of the Offering Documents demonstrates Silverback properly disclosed the relationship between SBT6050 and SBT6290, and the risks associated with SBT6290's future. For instance, the following statements were included in the Offering Documents:

> "SBT6290 is our second product candidate, expanding on the potential of a TLR8 agonist as a payload. The same TLR8 linker-payload used in SBT6050 is conjugated to a monoclonal antibody that targets Nectin4."

> "Future results of preclinical and clinical testing of our product candidates are also less certain due to the novel and relatively untested nature of our approach to TLR8 and related platform technologies. In general, clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits."

(Fukumura Decl. Ex. A at 3, 10 (Dkt. No. 48-6).)

> "We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. For example, we cannot begin our planned Phase 1 clinical trials for SBT6290, our Nectin4-targeted product candidate until we complete certain preclinical development and submit and receive authorization to proceed under INDs. We also dosed the first patient in a Phase 1/1b clinical trial for SBT6050 in July 2020 and cannot predict how our technology may work in solid tumor indications until we have completed dose-escalation and expansion."

(Fukumura Decl. Ex. B at 23 (Dkt. No. 48-7).)

And perhaps the most notable:

> "Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures."

(Fukumura Decl. Ex. C at 18.)

Plaintiffs' argument essentially asks the Court to find the Silverback had an extra obligation to spell out that it could not develop SBT6290's unless SBT6050's was successful. But there is no requirement that a company must draw out all inferences in order to provide a complete and accurate disclosure. And these disclosures are sufficient such that a reasonable investor would not have the impression that SBT6050's failure would not impact SBT6290's future. Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002) ("To be actionable under the securities law, an omission must be misleading; in other words, it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists.") Further, Plaintiffs point

to no data or documents that suggest Defendants knew they would have to discontinue SBT6290's development if SBT6050 failed.

Because Plaintiffs have failed to demonstrate that the omission that SBT6050's failure dooms SBT6290 is material and necessary to make the documents not misleading, their claim as to this statement fails. The Court GRANTS Silverback's Motion to Dismiss as to Plaintiffs' section 11 claims.

3. Section 10(b) and SEC Rule 10b-5 Claims

Section 10(b) and 10b-5 claims are subject to heightened pleading standards under the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule 9(b). The Court previously dismissed Plaintiffs section 10(b) claims for failure to meet these standards. Plaintiffs' SAC fails to cure the deficiencies.

a. Elements of Claim

Section 10(b) provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security. . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe. . ." 15 U.S.C. § 78j(b). SEC Rule 10b-5 makes it unlawful for any person to use interstate commerce:

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To prevail on a Section 10(b) claim, a plaintiff must prove "(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." Daou, 411 F.3d at 1014. At the pleading stage, a complaint stating claims under Section 10(b) and Rule 10b-5 must satisfy the dual pleading requirements of Rule 9(b) and the PSLRA. Id.

b. Falsity

Under the PSLRA, "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). "Falsity is alleged when a plaintiff points to defendant's statements that directly contradict what the defendant knew at the that time." Khoja v. Orexigen Therapeutics, Inc., 899 F.3d 988, 1008 (9th Cir. 2018). "Even if a statement is not false, it may be misleading if it omits material information." Id. "Disclosure is required . . . only when necessary to make . . . statements made, in light of the circumstances under which they were made, not misleading." Matrixx Initiatives, Inc. v. Siracusano, 53 U.S. 27, 44 (2011) (internal citation and quotation omitted). "[A] misrepresentation or omission is material if there is a substantial likelihood that a reasonable investor would have acted differently if the misrepresentation had not been made or the truth had been disclosed." Livid Holdings Ltd. v. Salomon Smith Barney, Inc., 416 F.3d 940, 946 (9th Cir. 2005). "In order to survive a motion to dismiss under the heightened pleading standards of the [PSLRA], the plaintiffs' complaint must specify the reason or reasons why the statements made by [defendant] were misleading or untrue, not simply why the statements were incomplete." Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002).

Silverback's Statements from March - August 2021

Plaintiffs' claim Silverback's March, May and August statements were false and misleading because they contained material omissions that: (1) the trial data demonstrated only limited anti-tumor activity despite the observed changes in the PD markers; (2) patients in Part 3 of the trial with SBT6050 in combination with pembro suffered cytokine related adverse events, meaning SBT6050 did not have a manageable safety profile ; and (3) if SBT6050 failed then SBT6290 would be discontinued. (SAC ¶¶ 71-73.)

Plaintiffs' allegations as to falsity for these statements fall short. Plaintiffs' theory of the case mistakenly relies on the trial's "open label" status. Plaintiffs mistake open label to mean that Silverback had access to trial data in real time. But that is not what open label means. As Defendants point out, an open label trial is defined as "[a] type of study in which both the health providers and the patients are aware of the drug or treatment being given." (Fukumura Decl. Ex. X (Dkt. No. 48-29).) It does not mean the data is gathered, cleaned, analyzed and summarized in real time. And though, hypothetically, a company could have access to data at all times, Plaintiffs would need factual allegations other than an "open label" status to demonstrate this. Silverback previously disclosed this did not occur for the Phase 1/1b trial. Instead, Silverback stated at the time of the IPO, in its Form 424B Prospectus, that:

> "We rely on third parties to conduct, supervise, and monitor our clinical trials and perform some of our research and preclinical studies."
>
> "We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves . . . Specifically, CROs that manage preclinical studies, GLP toxicology studies and our clinical studies as well as clinical investigators, and consultants play a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs."

(Fukumura Decl. Ex. D at 30 (Dkt. No. 48-9).)

To conduct the trial, Silverback utilized twelve clinical sites in three countries: the United States Australia and South Korea. (See Fukumura Decl. Ex. S at 7-8 (Dkt. No. 58-24.)

Plaintiffs allege that by no later than April 4, 2021, six days after the 10-K and a month before the 10-Q, ten out of fourteen patients demonstrated disease progression. (Response at 16.) Silverback disclosed this information in the Abstract on September 13, 2021, which had a data cutoff date of April 4, 2021. (SAC ¶ 12.) Plaintiffs emphasize this data cutoff date to argue that Silverback and the Exchange Act Defendants had access from the "open label" data from "day one" and they evaluated patients every few weeks and observed disease progression "well before the March 29, 2021, misstatements, knew no later than April 4, 2021, that ten out of fourteen patients in the first and third cohorts had progressive disease . . ." (Response at 17.) But again, Plaintiffs theory is based on a misunderstanding of open label and data cutoff dates.

Plaintiffs conflate data cutoff dates to mean the data had been gathered and reviewed by no later than that cutoff date. That is not generally what data cutoff means. (See Fukumura Decl. Ex. Y at 12 (Dkt. No. 48-30) ("A period of several weeks are commonly required for data cleaning and query resolution" after a data cutoff date). Plaintiffs essentially argue the Court should infer from the trial's open label that the twelve clinical sites located in the three countries were continuously cleaning and aggregating data, reviewing it, and summarizing it, and making it available before the data cutoff date, and that the Exchange Act Defendants, Silverback's CEO and CFO, had access to that information at any given moment.

But the only demonstrated facts are: (1) Third parties conducted and administered SBT6050 and evaluated patients; (2) Silverback had a data cutoff date of April 4, 2021; (3) the collected and analyzed data showed ten out of fourteen patients had progressive disease. Notably missing are any articulable facts that Silverback or the Exchange Act Defendants had access to

that data or knowledge of the disease progression prior to the data cutoff date or even a month later with the May 10-Q filing. And though it is possible that Silverback did not follow generalized practices, and Defendants had access to all the data at any given moment, the Court is unwilling to disregard generally accepted definitions and principals simply because Plaintiffs argue otherwise, but forth no evidence in support.

Even assuming, the Exchange Act Defendants were aware that disease progression occurred, that still does not make the statement that changes in the PD markers occurred misleading. As previously stated with regard to Plaintiffs' section 11 claim, Silverback's statements regarding changes in the PD markers makes clear that these changes had been associated with tumor regression in preclinical studies, not that these changes meant tumor regression occurred. For these reasons, Plaintiffs fail to plead falsity as to these statements.

Plaintiffs' arguments regarding safety data also fail. Plaintiffs claim that patients treated in Part 3 of the trial suffered cytokine related adverse events, which demonstrated SBT6050 did not have a manageable safety profile. (SAC ¶ 72.) Notably lacking are any allegations or facts that the Exchange Act Defendants knew this at the time the March and May statements were made. The only allegation Plaintiffs put forth is a sentence in the Response brief that both the Abstract and ESMO presentation shows these adverse events were demonstrated by the data collected by the cutoff dates. (Response at 21.) But again, cutoff dates alone do not demonstrate Defendants had that information at the time the statements were made. For the same reasons articulated above, Plaintiffs fail to plead falsity as to this statement.

Lastly, turning the Silverback's statements regarding SBT6290, the Court finds Plaintiffs fail to show the statements are misleading. Silverback made the following statements about SBT6290 in the March and May disclosures:

> "SBT6290 is our second product candidate, expanding on the potential of a TLR8 agonist as a payload. The same TLR8 linker-payload used in SBT6050 is conjugated to a monoclonal antibody that targets Nectin4 . . . We anticipate submitting the IND for SBT6290 in the fourth quarter of 2021."

(SAC ¶ 68.)

> "SBT6290 . . . continues to advance through preclinical development. SBT6290 includes the same TLR8 agonist linker-payload used in SBT6050, conjugated to a proprietary Nectin4-directed monoclonal antibody. Pre-Investigational New Drug (IND) alignment with the FDA was achieved in February 2021 and an IND application is expected in the fourth quarter of 2021. The initiation of a Phase 1/1b clinical study is anticipated in the first quarter of 2022."

(Fukumura Decl. Ex. F at 1 (Dkt. No. 48-11).)

Plaintiffs claim these statements are false and misleading because they do not disclose that if SBT6050 fails then SBT6290 would have to be discontinued as well. But these statements do not give the impression that SBT6290 will be developed regardless of SBT6050's outcome. They simply contain the drug's development thus far and Silverback's forward-looking statement as to future development plans. There is nothing to suggest that Silverback and the Exchange Act Defendants knew they would have to cease development of SBT6290 if SBT6050 failed. If anything, the omission would make the statement "incomplete," but there is nothing to suggest the statement is untrue or misleading. The Court finds these statements fail as to falsity.

Silverback's Statements in the Abstract and ESMO Presentation

In the SAC, Plaintiffs do not identify any false or misleading statements made in the Abstract or during the ESMO presentation. It is only in Plaintiffs' Response that they allege Silverback falsely stated: (1) proof-of-mechanism was established; (2) early signs of anti-tumor activity occurred; (3) SBT6050 conferred clinical benefit; and (4) SBT6050 had a manageable safety profile. (Response at 18.)

When placed in context the statements do not appear to be false. As Defendants correctly argue, the statements are accompanied by detailed clinical data that puts the statements into context. For instance, the ESMO presentation states "Proof-of-mechanism established" and then proceeds to explain this is supported by PD markers indicative of myeloid and T/NK cell activation that generally increased with the dose, and plateaued at 0.6 mg/kg. (Fukumura Decl. Ex. O at 8 (Dkt. No. 48-20.) And "[e]arly signals of anti-tumor activity" is accompanied by data that explains among eighteen evaluable patients, one patient showed a partial response and seven patients had stable disease. (Id.) Though Silverback's statements may be slightly optimistic, they are not necessarily false. And Silverback accompanied the statements with data that gives investors a full picture.

Plaintiffs argue that Defendants have no basis for making these statements, as well as statements regarding changes in the PD markers, given that the data only demonstrated limited anti-tumor activity and a high percentage of disease progression. But in order to allege falsity, Plaintiffs "must set forth facts explaining why the difference between two statements is not merely the difference between two permissible judgments, but rather the result of a falsehood." Rigel, 697 F.3d at 879. Plaintiffs essentially disagree with Silverback's analysis and conclusion of the data, but Plaintiffs are pointing to the same data Silverback used to support these conclusions, disclosed in the same documents, in support of their argument. Plaintiffs may disagree with Silverback's conclusion and the import of the data used in support of these conclusions, but it does not make the statements false or misleading.

With regard to Silverback's statement that SBT6050 had a manageable safety profile, Plaintiffs similarly fail to demonstrate falsity. Plaintiffs allege that the Exchange Act Defendants had a duty to disclose that dose limiting cytokine related adverse events meant that SBT6050 did

not have a manageable safety profile. Plaintiffs argue that Silverback knew by the ESMO presentation it would have to discontinue SBT6050 because of cytokine related adverse events, but waited until March 2022 to do so and did not identify any new data in support of that decision. (Response at 20-21.) But this is not true. In the ESMO presentation, Silverback's presentation stated that it was currently enrolling patients for Part 3 pembro combination dose escalation at 0.6 mg/kg. (Fukumura Decl. Ex. O at 9.) In Silverback's November 10-Q, it then states:

> Two patients dosed at 0.6 mg/kg each experienced a [dose-limiting toxicity], including hypotension and cytokine release syndrome (CRS) . . . Two patients were subsequently enrolled at a dose level of 0.45 mg/kg plus pembrolizumab . . .The second patient . . . experienced serious adverse events (SAEs) of CRS, hypoxia, and hypotension following the first dose . . and subsequently passed away.

(Fukumura Decl. Ex. P at 24 (Dkt. No. 48-21).)

Plaintiffs fail to point to any false information presented at the ESMO or in the Abstract that would make Silverback's statements on SBT6050's safety false, but instead rely on Silverback's November and March disclosures to allege falsity. For these reasons, Plaintiffs fail to adequately plead falsity as to these statements.

Silverback's November 10-Q filing

Lastly, Plaintiffs argue Silverback's 10-Q filing in November 2021 is false because: (1) Silverback continued to represent that SBT6050 conferred clinical benefit despite limited tumor activity; (2) SBT6050 did not have a manageable safety profile; and (3) Silverback failed to disclose that if SBT6050 failed SBT6290 failed as well. Plaintiffs fail to demonstrate falsity as to these statements. (SAC ¶¶ 93, 95, 96.)

The statements Plaintiffs highlight in the SAC as allegedly false statements regarding SBT6050's clinical benefit reiterates Silverback's findings from the September 2021 disclosures.

(SAC ¶¶ 92-93.) Plaintiffs point to no new statements Silverback made or data released, but simply repeat their accusations from the September disclosures. (Id.) This conclusory allegation of falsity fails for the same reason as before.

With regard to SBT6050's safety profile, Plaintiffs point to the data released that discusses the adverse events, including the dose-limiting toxicities and CRS that patients experienced at the higher dose levels in combination with pembro. (SAC ¶ 94.) Interestingly, this disclosure seems to highlight the issues emerging with regard to the safety of SBT6050 at higher dose levels. And Plaintiffs do not point to any statement by Silverback claiming that despite this information there were no concerns about SBT6050's safety. Plaintiffs do not point to anything at all that is false about this disclosure, but simply state that Silverback misled investors because the occurrence of the CRS in patients meant SBT6050 did not have a manageable safety profile. Again, Plaintiffs do not point to any data or reports that suggest Defendants knew at the time this statement was made. Instead, the statement accurately reports the safety issues and states the patients subsequently were enrolled at a lower dose level. Because Plaintiffs cannot point to any other statement made by Silverback that contradicts this disclosure, this statement fails to demonstrate falsity.

Finally, Silverback's statement discussing SBT6290, what it is designed to do and where it was in the developmental stage, is the same disclosure Silverback had made multiple times previously. (SAC ¶ 96.) Again, Plaintiffs claim Silverback had a duty to disclose that SBT6290's fate was tied to SBT6050's success. Similar to the previous statements, Plaintiff point to nothing false or even misleading about this statement. This statement is at most incomplete, which does not make it false or misleading. Plaintiffs' claims as to this statement fails.

For all the reasons articulated above, the Court finds Plaintiffs have failed to meet the pleading requirements for falsity under Rule 9(b) and the PSLRA. The Court GRANTS Defendants' Motion as to Plaintiffs' section 10(b) claim.

c. Scienter

Plaintiffs also fail to advance sufficient allegations of scienter.

A Section 10(b) fraud complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "The court must determine whether all the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 9or81, 991 (9th Cir. 2009) (internal citation and quotation omitted). When "determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." Id. Essentially, a complaint survives a motion to dismiss "if the malicious inference is at least as compelling as any opposing innocent inference." Id.

To adequately demonstrate that the "defendant acted with the required state of mind," a complaint must "allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." Daou, 411 F.3d 1014-15 (internal citation omitted). Critically, deliberate recklessness is more than recklessness or motive to commit fraud – it is "an *extreme* departure from the standards of ordinary care," which "presents a danger of misleading buyers or sellers that is either known to the defendant or so *obvious* that the actor must have been aware of it." Zucco Partners, 552 F.3d at 991 (emphasis in the original).

Plaintiffs argue Silverback's statements during the class period were misleading because they failed to disclose: (1) only limited anti-tumor activity despite changes in the PD markers; (2) patients treated in part 3 of the trial suffered cytokine related adverse events that

demonstrated SBT6050 did not have a manageable safety profile; and (3) Silverback would have to discontinue SBT6290 if SBT6050 failed. (SAC ¶¶ 71, 72, 73, 75, 77, 78, 89, 93, 95, 97.) Plaintiffs' claims fail because they fail to adequately plead scienter, for many of the same reasons that they fail for falsity. See Daou, 411 F.3d at 1015 ("[F]alsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, and the two requirements may be combined into a unitary inquiry under the PSLRA.")

Plaintiffs' argument in support of scienter hinges on their belief that Silverback and the Exchange Act Defendants had access to data at all times due to the trial's open label status. (SAC ¶ 102.) But again, Plaintiffs' argument is flawed because it fundamentally misunderstands what open label means. As Defendants and this Court have repeatedly pointed out, open label simply means both the patient and the researcher are aware what drug is given and when. It does not mean Silverback and the Exchange Act Defendants had access to data in real time.

And Plaintiffs conflate data cutoff dates to mean the data had been gathered and reviewed by that date. Plaintiffs essentially argue the Court should infer from the trial's open label that the twelve clinical sites located in the United States, Australia, and South Korea were continuously aggregating data, reviewing it, and summarizing it before the data cutoff date, and that the Exchange Act Defendants had access to that information at any given moment. But Plaintiffs' point to no particularized facts that suggest that the data had been gathered and reviewed by the individual Defendants prior to the cutoff dates and the Court is unwilling to make such an inferential leap. "[T]he PSLRA neither allows nor requires us to check our disbelief at the door." Nguyen v. Endologix, Inc., 962 F.3d 405, 415 (9th Cir. 2020) ("'Plausibility' is a concept more commonly associated with the base-level 'non-fraud' pleading standards in Rule 12(b)(6).") Even if the Court could assume Silverback and the Defendants had access to data in real time,

the Ninth Circuit previously held that knowledge alone is insufficient to plead scienter. See In re Rigel Pharms., Inc. Sec. Litig., 697 F.3d 869, 883 (9th Cir. 2012) ("Even assuming, arguendo, that Plaintiff adequately pled that all of the defendants had knowledge of the detailed clinical results at the time the allegedly false statements were made, such an allegation does not support a strong inference of scienter.")

Plaintiffs' argument that because Defendant Shawver held company wide meetings every two weeks to discuss trial data means the Exchange Act Defendants had the requisite knowledge, but deliberately omitted material information is equally flawed. In response to Defendants' first motion to dismiss, Plaintiffs put forth a Confidential Witness ("CW") 1 for the general premise that the bi-weekly meetings occurred, and mandatory attendance was required. The Court in response to CW1 found these allegations to be insufficient to support scienter, in part because CW1 put forth no specific details about what was discussed during the meetings that would demonstrate the Exchange Act knew their statements were false and misleading. Plaintiffs put forth no additional information in the SAC than they did in the first. Again, CW1 states that "Defendant Shawver held company wide meetings every two weeks with mandatory attendance for all employees to report and discuss trial data." (SAC ¶ 57.) The mandatory attendance is all Plaintiffs have to suggest that CFO Defendant Piazza was present, and it is the only allegation Plaintiffs have to claim Defendant Piazza had any information related to the trial. (Response at 23.)

Again, Plaintiffs ask the Court to make inferential leaps unsupported by the facts. Despite having CW1, Plaintiffs put forth no specific allegations that the meetings discussed concerns that emerging data showed limited anti-tumor activity and poor safety outcomes, or that this data

meant SBT6290 was doomed. Plaintiffs' utilization of CW1 falls well short of the detailed factual allegations needed for scienter.

The Ninth Circuit's reasoning in Nguyen v. Endologix, Inc., 962 F.3d 405 (9th Cir. 2020) is instructive here. In Nguyen, plaintiffs alleged that a medical device company and its officers made false or misleading statements about the likelihood that the Food and Drug Administration would approve of the company's aneurysm sealing product. Plaintiffs' complaint relied heavily on a confidential witness who worked at the company and alleged that the product had migration issues, meaning it moved away from the location where it was initially placed, which can cause serious health issues. Id. at 408-09. The complaint alleged the confidential witness was involved in the development of the product from the start and from early on the company received complaints and incident reports regarding the migration. Id. at 409. The confidential witness alleged the main defendants became very involved in the problem, putting everything into solving it and that the issue was the "biggest thing going on at the company." Id. at 409-410. In further support of this allegation, the confidential witness claimed he and other staff compiled weekly reports about the migration issue for the main defendants, but that ultimately, the defendants failed to act on or fully disclose the information. Id. at 410.

The Ninth Circuit found that the allegations were high on alarming adjectives, such as "serious and unsolvable," "dangerous," "urgent" and so on, but short on facts. Nguyen, 962 F.3d at 416. The main problem with the confidential witness was that the information attributed to them lacked any detail about the migration device problems the company encountered. Id. For instance, the witness did not identify the number of patients that experienced migration, how much the device was migrating in these patients, whether the migration led to any medical issues, and whether the patients had particular conditions that exacerbated the migrations. Id. The

Ninth Circuit found that "while CW1 references a 'stream of complaints and incident reports and a general concern that these reports supposedly cause, the complaint does not plead any details about these reports that would demonstrate a strong inference of scienter in [defendants] later statements about FDA approval or [device] migration." Id. at 417.

Here, CW1's statements do not even meet the level of specificity described by the plaintiffs' confidential witness in Nguyen. Despite being employed as a senior research scientist and an associate scientist for Silverback, CW1 does not discuss any specifics of what was shared during the bi-weekly meetings or even allege that negative data or reports existed. CW1 does not even confirm that Defendant Piazzo actually attended the meetings. Instead, the Court is asked to again infer that because all employees were required to attend the meetings, Defendant Piazzo attended as well, and that concerns regarding efficacy, safety and SBT6290 were discussed. The Court is unwilling to make these inferential leaps. The Court finds CW1's claim that Defendant Shawver held bi-weekly meetings insufficient to demonstrate a strong inference of scienter.

Finally, Plaintiffs argument that the core-operations inference is a sufficient basis for scienter also fails. The core-operations inference stands for the proposition that "facts critical to a business's core operations or an important transaction generally are so apparent that their knowledge may be attributed to the company its key officers under the PSLRA." S. Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 783 (9th Cir. 2008). "Allegations that rely on the core-operations inference are among the allegations that may be considered in the complete PSLRA analysis." Id. at 784. "Where a complaint relies on allegations that management had an important role in the company but does not contain additional detailed allegations about the defendants' actual exposure to information, it will usually fall short of the PSLRA standard." Id. Only in unusual circumstances will the core-operations inference, without more, raise the strong

inference required. Id. at 785. For instance, the Ninth Circuit in Berson v. Applied Signal Technology, Inc. 527 F.3d 982 (9th Cir. 2008) permitted a plaintiff to rely on the core operations inference without particularized allegations about defendants' access to relevant information because defendants had allegedly failed to disclose a "stop-work order" from its largest customers, which halted between $18 and $23 million of work that made up roughly 80% of the company's revenue.

That is hardly the case here. Here, plaintiffs allege that at the time of the Phase 1/1b trial, Silverback had no approved product, revenue or other product undergoing clinical testing, which therefore means that SBT6050 must have been the sole focus of the company and the Exchange Acts Defendants. Plaintiffs then argue that the most compelling inference of this "is that each Defendant monitored the open label trial data of their lead drug candidate and only drug in active development and thus had knowledge of the matter." (Response at 23.) But this is merely a conclusory allegation based on nothing more than the trial's open label. Plaintiffs do not point to any facts to suggest that Defendants acted with the requisite scienter.

Overall, the inference of scienter here is weak and certainly falls well below the required strong inference needed to survive a motion to dismiss. The Court finds Plaintiffs failure to adequately plead scienter as an additional ground to dismiss the claim.

4. Section 15 and 20(a) Claims

Section 15 and section 20(a) both require underlying primary violations of the securities laws. 15 U.S.C. §§ 77o, 78t(a); Rigel Pharms, 697 F.3d. Because Plaintiffs have failed to adequately plead a violation of the federal securities laws, Plaintiffs' section 15 and section 20(a) claims are also DISMISSED.

CONCLUSION

Plaintiffs' Second Amended Complaint fails to allege with particularity that Silverback and the individually named Defendants made materially misleading statements and omissions in the Offering Documents and during the class period in violation of section 11 of the Securities Act and section 10(b) of the Exchange Act. Because the Court previously dismissed Plaintiffs' First Amended Complaint without prejudice and the Second Amended Complaint fails for the same reasons, the Court DISMISSES Plaintiffs' Second Amended Complaint with prejudice.

The clerk is ordered to provide copies of this order to all counsel.

Dated April 12, 2023.

Marsha J. Pechman
United States Senior District Judge